

How to Create a SMART IRB Reliance Agreement Request

USC is a participating institution of the SMART IRB and prefers to use the SMART IRB on-line platform to execute the study-specific reliance agreement. Below are the steps to complete in iStar and to register the study in SMART IRB:

1. You will need to indicate in iStar section 6d.1.8 under the site that the reliance agreement will be done via “SMART IRB”.
2. You will also need to create an account in SMART IRB at <https://smartirb.org/reliance/> . Once the USC IRB receives the request, THE USC IRB will grant you access to the platform. You will receive an email notification once your account is activated.
3. Once your account is activated, you will need login to the SMART IRB website at <https://smartirb.org/reliance/> and register the study. Guides and tutorials on how to register the study are also available on this site.
4. You will need to enter the study details and the **non-USC** site information. The title of the reliance request should **include the USC IRB number** and **have the same study title listed in iStar** since the USC IRB will need to verify the information in the reliance request with the information in the iStar study application.
5. The USC IRB will review the reliance agreement request and if the information is accurate and complete, the USC IRB will move the reliance agreement forward. The SMART IRB reliance checklist is attached for your reference.
6. You should also have the **non-USC** study team contact their IRB. The relying institution’s point of contact will receive notification from SMART IRB to access the online system and enter their reliance decision. Each relying institution will follow their own additional processes as needed for reliance documentation.
7. Once the relying institution accepts to rely on the USC IRB, the USC IRB will complete the necessary activities in the SMART IRB online system to execute the agreement.
8. Once the reliance agreements have been completed for each site, you will receive the determination letter for the reliance agreement. The determination letter should be uploaded to iStar section 6d.1.8 for each site listed in the reliance agreement.

NOTE: The relying site(s) cannot be approved by the USC IRB to participate in the study until the reliance agreement has been completed for the site(s) via the SMART IRB platform.



Initiating a request in the Online Reliance System

Initiating a reliance request

An investigator, or their designee, can submit a request for IRB reliance. At this time, institutions cannot submit requests on behalf of the investigator.

1. Log in to the [Online Reliance System](#) and click “New Request”.
2. Provide information about your study:
 - Basic information about the research (title of study, a brief description)
 - Name of the Principal Investigator
 - Select the institution that you would like to serve as the Reviewing IRB
 - Funding sources (optional)
 - List the sites that will be engaged in human subjects research for the study
 - For each site:
 - The site investigator’s name and contact information
 - Research personnel names and contact information (optional)
 - Research participants and activities
 - Upload supporting documents (PDFs only):
 - Research protocol
 - Consent templates (optional)
 - Other documentation (optional)
3. Review the request for accuracy.
4. Submit the request. You can log back in to the [Online Reliance System](#) to track the progress of your request. You will be notified by email once a reliance decision has been reached.

Questions? We’re here to help.

Contact us at help@smartirb.org.

Note: This form is only for reference purposes and represents an example of the online form. To submit a reliance request, log in and use the online form within the Online Reliance System.

* = Required Field

PI / Study

Title of Research Study*

Overall Principal Investigator (PI) Information

The Overall PI is the principal investigator who initiates and assumes leadership and has ultimate responsibility for the conduct of, and to ensure the safety and data integrity for, this Research Study.

First Name*

Middle Name

Last Name*

Home Institution*

Please indicate the institution or School that employs you. If you have appointments from multiple institutions, please select the institution from which you receive your paycheck.

Email Address*

Degree(s)*

Please check all that apply. If the exact degree isn't listed, use the closest equivalent.

- | | | |
|------------------------------|-------------------------------|---------------------------------|
| <input type="checkbox"/> BA | <input type="checkbox"/> DDS | <input type="checkbox"/> MD |
| <input type="checkbox"/> BS | <input type="checkbox"/> DMD | <input type="checkbox"/> OD |
| <input type="checkbox"/> MA | <input type="checkbox"/> DNP | <input type="checkbox"/> PharmD |
| <input type="checkbox"/> MBA | <input type="checkbox"/> DrPH | <input type="checkbox"/> PhD |
| <input type="checkbox"/> MPH | <input type="checkbox"/> DVM | <input type="checkbox"/> ScD |
| <input type="checkbox"/> MS | <input type="checkbox"/> JD | <input type="checkbox"/> Other |

Phone*

Research Study Information

Brief Description of
Research Study*

Requested Reviewing
IRB*

The Overall PI's Home Institution will have the first option of electing to serve as the Reviewing IRB. The Home Institution will consider the proposal of an alternate Reviewing IRB, as appropriate.

Reason for requesting this institution*

Please check all that apply.

- PI Home Institution IRB
- Confidentiality/privacy concerns
- Conflict of interest issues
- Concerns regarding need for oversight
- Expertise concerns
- Grant-holding Institution
- Location of research activities
- Proposed Reviewing IRB has already reviewed this study or a similar/related study
- Research subject population
- Risk considerations
- Sensitivity of research
- Student involvement
- Feedback from Institutional Official, Chair, others, IRB
- Other clinical research infrastructure considerations
- Other

Funding Details (if applicable)

Multiple sources may be added.

Funded by*

Primary Awardee
Institution*

Funding Type*

Please check only one.

- Federal Government
- State Government
- Industry
- Other

Sites Involved in the Research

Multiple sites may be added.

Site Name*

Site Investigator (SI) Information

There can only be one designated SI per institution. You will have the opportunity to add additional research personnel later.

First Name*

Middle Name

Last Name*

Degree(s)*

Please check all that apply. If the exact degree isn't listed, use the closest equivalent.

- | | | |
|------------------------------|-------------------------------|---------------------------------|
| <input type="checkbox"/> BA | <input type="checkbox"/> DDS | <input type="checkbox"/> MD |
| <input type="checkbox"/> BS | <input type="checkbox"/> DMD | <input type="checkbox"/> OD |
| <input type="checkbox"/> MA | <input type="checkbox"/> DNP | <input type="checkbox"/> PharmD |
| <input type="checkbox"/> MBA | <input type="checkbox"/> DrPH | <input type="checkbox"/> PhD |
| <input type="checkbox"/> MPH | <input type="checkbox"/> DVM | <input type="checkbox"/> ScD |
| <input type="checkbox"/> MS | <input type="checkbox"/> JD | <input type="checkbox"/> Other |

Email Address*

Phone*

A number where we can reach you directly, e.g., cell phone.

Site Details

Research Personnel

Please list all other research personnel involved in this study for each site.

Role*

First Name*

Last Name*

Degree(s)*

Please check all that apply. If the exact degree isn't listed, use the closest equivalent.

- | | | |
|------------------------------|-------------------------------|---------------------------------|
| <input type="checkbox"/> BA | <input type="checkbox"/> DDS | <input type="checkbox"/> MD |
| <input type="checkbox"/> BS | <input type="checkbox"/> DMD | <input type="checkbox"/> OD |
| <input type="checkbox"/> MA | <input type="checkbox"/> DNP | <input type="checkbox"/> PharmD |
| <input type="checkbox"/> MBA | <input type="checkbox"/> DrPH | <input type="checkbox"/> PhD |
| <input type="checkbox"/> MPH | <input type="checkbox"/> DVM | <input type="checkbox"/> ScD |
| <input type="checkbox"/> MS | <input type="checkbox"/> JD | <input type="checkbox"/> Other |

Email Address*

Research Participants and Activities

Please provide information on the research activities that will take place at this site.

Please check all that apply.

Type(s) of Research Participants at this Site*

- | | |
|--|--|
| <input type="checkbox"/> No subjects | <input type="checkbox"/> Prisoners |
| <input type="checkbox"/> Healthy controls | <input type="checkbox"/> Persons with impaired decision making |
| <input type="checkbox"/> Adults (as defined by state law) | <input type="checkbox"/> Students |
| <input type="checkbox"/> Newborns, Infants | <input type="checkbox"/> Employees/Staff in Dept/Unit/Lab (vs general recruitment) |
| <input type="checkbox"/> Children age 2 and over (as defined by state law) | <input type="checkbox"/> Other |
| <input type="checkbox"/> Pregnant Women/Fetuses | |

Activities at this Site*

- | | |
|---|--|
| <input type="checkbox"/> None | <input type="checkbox"/> Research Interactions |
| <input type="checkbox"/> Medical Records Review | <input type="checkbox"/> Recruitment |
| <input type="checkbox"/> Obtaining Informed Consent | <input type="checkbox"/> Other |

Specimen use at this Site*

- | | |
|-----------------------------------|---|
| <input type="checkbox"/> None | <input type="checkbox"/> Collection |
| <input type="checkbox"/> Analysis | <input type="checkbox"/> Creation of Repository |
| <input type="checkbox"/> Banking | |

Data Analysis of Health Information*

- | | |
|--|--|
| <input type="checkbox"/> No data analysis will be conducted at this site | <input type="checkbox"/> De-identified but hold a code |
| <input type="checkbox"/> Anonymous | <input type="checkbox"/> Identifiable |
| <input type="checkbox"/> De-identified | |

Research Data*

- | | |
|---|---|
| <input type="checkbox"/> No research data will be retained at this site | <input type="checkbox"/> Will be kept at another location or sent offsite |
| <input type="checkbox"/> All or most of the research records and research related information will be retained at this site | |

Ancillary Services utilized at this site requiring other institutional reviews*

- | | |
|---|---|
| <input type="checkbox"/> None | <input type="checkbox"/> Nursing |
| <input type="checkbox"/> Biostatistics | <input type="checkbox"/> Radiation Safety (exposure to ionizing radiation or administration of radiopharmaceutical) |
| <input type="checkbox"/> Biomedical Engineering | <input type="checkbox"/> Other |
| <input type="checkbox"/> Pharmacy | |

Supporting Documents

Documents containing protected health information (PHI) as defined by HIPAA should not be uploaded to Reliance.

All documents must be PDFs, smaller than 10Mb, and have a unique file name.

Upload:

- **Research Protocol***
- **Consent Template(s) (If applicable)**
- **Other Documentation**